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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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GORE ENTERPRISE HOLDINGS, INC.
551 PAPER MILL ROAD
P. O. BOX 9206
NEWARK, DE 19714-9206

EXAMINER	
ISABELLA, DAVID J	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/737,324	CULLY ET AL.	
	Examiner	Art Unit	
	DAVID J. ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 21-34* is/are pending in the application.

4a) Of the above claim(s) *7 and 24-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-19,21,22,29-34* is/are rejected.

7)☐ Claim(s) *23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The RCE and the corresponding amendment filed 4/26/2006 has been entered. Claims 1-19,21-34 are currently pending, with claims 7 and 24-28 being withdrawn. The claims being considered for further examination on the merits are claims 1-6, 8-19,21-23 and 29-34.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al. (USPN 5,799,384 as cited in applicant's IDS).

Schwartz et al. discloses a method of making a removable stent-graft with all the elements of claim 34. See Figures 1-4 and column 5, lines 51-52 for providing a stent component (4) having a helical orientation having a pitch, and for providing the stent component (4) with a graft material (8) that covers one side of the stent component (4). See column 4, lines 65-67 for the graft material (8) overlapping adjacent stent elements (14), thereby covering the spaces between adjacent stent elements (14) in a substantially continuous fashion. Because the overlapped portions of the graft material

(8) are not attached to each other, the graft material (8) is capable of being split (defined as "separated") in a direction parallel to the pitch of the helical orientation of the stent component (4).

The limitation of "substantially integral and continuous fashion, wherein the graft material is splittable between adjacent elements of the stent component" fails to distinguish over the same as disclosed by Schwartz et al.

Applicant argues that Schwartz et al windings are never joined to form a continuous luminal surface and thus remain separate and discrete. First, the claim fails to define the luminal surface as being continuous. Second, contrary to applicant's arguments, the windings of Schwartz et al results in a continuous surface which meets the limitations of the claim, as broadly worded.

Applicants respectfully disagree with the Examiner's position. First (as recognized by the Examiner), Schwartz et al. do not teach or suggest removability of their device following implantation. Second, Schwartz et al. does not teach or suggest splittability as taught by the present application. If the helical windings are never joined to form a substantially continuous luminal surface and thus remain separate and discrete "layers," they cannot be said to be "splittable" as presently claimed.

The "splittable" character of the present invention is described at page 4, lines 16-20, page 11, lines 1-18 and (for example) by Figure 2. The Examiner states that the term "splittable" is not defined explicitly and notes that while claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Applicants' position is that the "splittable" limitation is suitably defined and that no additional specification limitation is being read into the claim. As noted previously, the helical windings with their attached tape of film taught by Schwartz et al. are not joined and are separate and discrete. As such, they do not meet the requirement of the present amended claim for a graft covering that "...covers spaces between adjacent elements of the stent component in a substantially integral and continuous fashion..." Accordingly, the present claim is not anticipated by the graft covering taught by Schwartz et al.

With respect to the function of splittable, examiner maintains the arguments presented supra. As broadly worded, splittable does not inherently possess the meaning as set forth in the specification. The specification defines the graft material to be selectively weakened in a prescribed manner. If applicant desires the claims to possess the meaning as ascribed by applicant, then applicant should amend the claims to include language that the graft material is prescribed with selectively weakened pattern that will result in splitting of the material.

> Numerous means for rendering the graft material 18 able to be cohesively disassembled can be contemplated. Figure 4A shows a device 10 wherein the graft material 18 is selectively weakened in a prescribed pattern 34. The graft material 18 may be weakened in those areas 34 by mechanical means such as a cutting with a blade or compressing die. Alternatively the graft material 18 may be weakened by use of energy such as with a laser or controlled heating. While the patterns 34 may extend entirely through the wall of the graft material 18, it is preferred that they only extend through a portion of the thickness of the graft material.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 8-10, 12-15, 17-20, 22 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. in view of Bosley, Jr. (USPN 5,514,176 as cited in applicant's IDS).

Schwartz et al. discloses an endoprosthesis with all the elements of claims 1 and 33, but is silent to the endoprosthesis being adapted to be cohesively disassembled to allow for its remote removal from a patient. See Figures 2-5 for an endoprosthesis (10) comprising a structural support in the form of a stent component (4) having a small delivery profile (Figures 6 and 7) and an enlarged deployed profile (Figure 8), and adjacent elements (14) with space therebetween (Figure 5). A graft material (8) is attached to the stent component (4) covering the space between stent elements (14) to form an integral and continuous luminal surface (column 4, lines 65-67). See Figure 5 and column 4, lines 48-50 for the stent (4) being in the form of a coil and column 5, lines 60-62 for the stent (4) being made from tantalum or stainless steel. Bosley, Jr. teaches a coil stent (10) made from tantalum or stainless steel that includes a tag end (22) for being gripped by forceps for the cohesive disassembly of the stent (10) for removal from the patient. See Figure 9, column 4, lines 46-49 and 65-65 and column 7, lines 7-9. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Bosley, Jr. to modify the stent component (4) of Schwartz et al. by including a tag end (22) on the end thereof that is grippable by forceps. Because the stent material (tantalum or stainless steel) of Schwartz et al. is the same as that of Bosley, Jr., the stent of Schwartz et al. is modified to include the tag end of Bosley, Jr., and the graft material (8) of Schwartz et al. has strain relief in the form of a slit or v-shaped cut, the endoprosthesis of Schwartz et al. is adapted to be cohesively disassembled for its remote removal from the patient.

Applicant argues that the current amendment "integral and continuous" distinguishes over Schwartz et al. Examiner respectfully disagrees with applicant's position. It appears applicant is reading. more narrowly, the meaning of integral and continuous. The overlapping of the graft material (8) that covers one side of the stent component (4) results in the covering of the spaces between adjacent stent elements (14) in a substantially continuous fashion. Integral does not mean unitary or one-piece and as a whole the graft in combination with the stent forms an integral surface.

Claim 2 includes only functional language and fails to further structurally limit the claimed invention. The graft material (8) is structurally capable of tearing, particularly at the point of the slit or v-shaped cut (Figure 3), which is between the adjacent elements of the stent component.

Claims 3-6, 8 and 9, see Figures 8 and 9 of Bosley, Jr. When the tag end applied to the stent of Schwartz et al. is gripped and pulled, the endoprosthesis (10) will be removable at a profile less than the enlarge deployed profile and the small delivery profile by disassembling in a helical fashion in a single piece. The endoprosthesis will increase in length by at least 500%.

Claim 10, see column 4, lines 8-10 for the graft material (8) being impermeable.

Claims 12 and 13, see Figure 8 as compared to Figure 7 for the endoprosthesis (10) being adapted to be controllably foreshortenable by at least about 50%.

Claim 14, see rejection to claim 1, supra. Also see column 5, lines 51-52 for the graft material (8) being attached to the stent (4) and Figure 3 for the graft material (8)

including slits of v-shaped cuts, thereby making the graft material (8) adapted to be cohesively disassembled during removal of the endoprosthesis from a patient.

Claim 15, see column 7, lines 21-23 of Bosley, Jr. for the removal being atraumatic.

Claims 17-20, see Figures 1-4, column 4, lines 37-50 and 65-67 for the graft material (8) comprising a tape, wherein the tape and stent component (4) are helically oriented at substantially the same pitch angle. Because the graft material (8) tape is overlapping adjacent stent elements (14) without being attached thereto, the tape is adapted for splitting (defined as "separating") along the length of the tape.

Claim 22, see Figure3 for the graft having means for splitting (defined as "separating") in the form of slits or v-shaped cuts.

Claims 11, 16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. and Bosley, Jr. as applied to claims 1 and 20 above, and further in view of Smith (USPN 6,364,904, as cited in previous office action).

Schwartz et al., as modified by Bosley, Jr., discloses an endoprosthesis with all the elements of claims 1 and 20, but is silent to the additional limitations of the graft material being permeable and comprising ePTFE, as required by claims 11, 16 and 21. Smith teaches an endoprosthesis in the form of a stent-graft, wherein the graft is made from ePTFE in order to provide the endoprosthesis with a microporous structure that allows natural tissue ingrowth and cell endothelialization for long term healing and patency of the graft. See column 1, lines 54-60 and column 9, lines 40-41. It would

have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Smith to modify the endoprosthesis of Schwartz et al. by making the graft from ePTFE, which is by nature permeable, in order to provide the endoprosthesis with a microporous structure that allows natural tissue ingrowth and cell endothelialization for long term healing and patency of the graft.

10. Claims 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. in view of Cully et al. (WO 00/42949 as cited in applicant's IDS).

Schwartz et al. discloses an endoprosthesis with all the elements of claim 29, but is silent to at least one of the apices being raised to protrude outwardly from the tubular form and wherein the resulting raised apex is covered by the graft material. See Figures 1-4 and column 4, lines 17-51 for an endoprosthesis (10) comprising a stent component (4) comprising a wire (2) formed into a generally helical winding having a space between adjacent elements (14) of the generally helical winding (Figure 5). The generally helical winding provides a generally tubular form to the stent component (4) and wherein the generally helical winding includes at least one apex (Figures 1-3). A graft material (8) is attached to the stent component (4) covering the space between adjacent elements (14) to form a continuous luminal surface (column 4, lines 65-67). Cully et al. teaches an endoprosthesis (10) wherein at least one apex (15) located between the ends of the stent (11) is raised to protrude outwardly from the tubular form in order to provide as anchoring means by protruding slightly into the wall of the conduit into which it is implanted. See Figure 1 and page 6, lines 27-31. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the

teachings of Cully et al. to modify the endoprosthesis of Schwartz et al. by making at least one of the apices located between the ends of the stent component raised to protrude outwardly from the tubular form in order to provide the endoprosthesis (10) with an anchoring means by the apex protruding slightly into the wall of the conduit into which it is implanted. Because the wire (2) forming the stent component (4) is attached to the graft material (8), and the graft material (8) overlaps adjacent elements (14) (column 4, lines 65-67), the raised apex will be covered by the graft material (8) while the graft material (8) continues to provide a continuous luminal surface.

Claim 31, see Figure 4 for the generally helical winding having a serpentine form with alternating opposing apices.

Claims 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. and Cully et al. as applied to claims 29 and 31 above, and further in view of Bosley, Jr.

Schwartz et al., as modified by Cully et al., discloses an endoprosthesis with all the elements of claims 29 and 31, but is silent to the endoprosthesis being adapted to be cohesively disassembled to allow for its remote removal from a patient. See Figure 5 and column 4, lines 48-50 for the stent (4) being in the form of a coil and column 5, lines 60-62 for the stent (4) being made from tantalum or stainless steel. Bosley, Jr. teaches a coil stent (10) made from tantalum or stainless steel that includes a tag end (22) for being gripped by forceps for the cohesive disassembly of the stent (10) for removal thereof from the patient. See Figure 9, column 4, lines 46-49 and 65-65 and

column 7, lines 7-9. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Bosley, Jr. to modify the stent component (4) of Schwartz et al. by including a tag end (22) on the end thereof that is grippable by forceps. Because the stent material (tantalum or stainless steel) of Schwartz et al. is the same as that of Bosley, Jr., the stent of Schwartz et al. is modified to include the tag end of Bosley, Jr., and the graft material (8) of Schwartz et al. has strain relief in the form of a slit or v-shaped cut, the endoprosthesis of Schwartz et al. is adapted to be cohesively disassembled for its remote removal from the patient.

Response to Arguments

Applicant's arguments filed 4/26/2006 fully considered but they are not persuasive.

With respect to the rejection of claim 34 under 35 U.S.C. 102(b) as anticipated by Schwartz et al., applicant firstly argues that Schwartz et al. do not teach or suggest removability of their device following implantation. While the examiner agrees with the statement, it is not required that Schwartz et al. expressly disclose the stent-graft as being removable. Because claim 34 is a "method of making" claim, the stent-graft of Schwartz et al. is only required to be structurally capable of being removed following implantation, which it is. Applicant secondly argues that because the helical windings of Schwartz et al. are never joined and are separate and discrete layers, they cannot be considered "splittable" as described in the specification and drawings. In response, it is noted that "splittable" is not defined in the rejected claim(s). Although the claims are

interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Because the term "splittable" is not defined explicitly and with reasonable clarity, deliberateness and precision in the specification, but is rather simply described, "splittable" can be given its plain meaning (see *Teleflex Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001), and MPEP 2111.01). Therefore, using the dictionary definition of "splittable", the graft material simply needs to be capable of being separated, which it is at its overlapping portions. Schwartz et al. still reads on amended claim 34 because the overlapped portions of the graft material provide a covering of the spaces between adjacent elements of the stent component in a substantially continuous fashion. There are no gaps or spaces in the graft material because the graft materials in the overlapped portions are one on top of and in contact with each other.

With respect to the rejection of claims 1 and 33 under 35 U.S.C. 103(a) as unpatentable over Schwartz et al. in view of Bosley, Jr., applicant argues that the continuous character of the graft material of the present invention, as described in the specification, is entirely different from the overlapping film strip of Schwartz et al. The examiner disagrees. Again, the portions of the graft material forming the overlapping portions are on top of and in contact with each other. So even though the portions are not sealed, they do not create a gap or space therebetween. Therefore, the overlapping graft material does indeed from a continuous luminal surface.

In response to applicant's argument that due to the required abutment of the adjacent coils of Bosley, Jr., the reference cannot be combined with Schwartz et al. in that Schwartz et al. specify a space between adjacent windings of their serpentine wire that are spanned by the strip of flexible film attached to each winding, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Bosely, Jr. is used as a secondary reference only to teach removability of the endoprosthesis by cohesive disassembly. Including a tag, as taught by Bosely, Jr., to the end of the stent component of Schwartz et al. in order to allow for the stent-graft to be removed by cohesive disassembly is neither taught away from by Schwartz et al., nor destructive to the stent-graft.

With respect to amended claim 2, applicant argues that the tearing of the graft material during disassembly occurring between adjacent elements of the stent component is not met by Schwartz et al. The examiner disagrees. The slits or V-shaped cuts, which are located between adjacent elements of the stent component, allow for strain relief to those areas of the graft material during expansion of the stent component. When tension is applied to the wire end to cause unwinding, it is those areas of the slits or V-shaped cuts that will experience the greatest strain. It is therefore, those areas that are capable of tearing during disassembly.

With respect to claim 10, applicant argues that the graft material of Schwartz et al. is hardly impermeable with the adjacent edges of each helical wining of the flexible film not being sealed together in any way. In response, applicant's attention is directed to the exact wording of claim 10, which requires the graft material to be impermeable. According to column 4, lines 9, the graft material of Schwartz et al. can be made from the impermeable material polyurethane. The claim does not require that structure formed by the graft material be impermeable.

With respect to claims 12 and 13, applicant argues that Figures 7 and 8 of Schwartz et al. does not indicate foreshortening and that the specification is silent as to foreshortening. Figures 7 and 8 were pointed out by the examiner to show the structural change to the stent during expansion. The stent is certainly capable of being controllably foreshortened, such as by applying inwardly directed forces on the ends of the stent during expansion outside of the body. In a product claim such as claim 10, the endoprosthesis simply needs to be structurally capable of being controllably foreshortenable by the required percentages. It is not required that Schwartz et al. expressly disclose that this is what the endoprosthesis is adapted to do.

With respect to the arguments directed to the rejection of claim 14, see the response to claim 1, supra, for the graft material indeed being adapted to be cohesively disassembled during removal of the endoprosthesis from a patient. The overlapping portions of the graft material form a continuous luminal surface and will split (separate) during removal.

With respect to claim 15, applicant argues that Bosley, Jr. still requires the abutted coils that are contrary to claim 1 of the present invention. Again, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In response to applicant's argument of the rejection of claims 17-20 and 22 that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., tape of the graft material having *adjacent edges that when helically wound are joined together* produce a continuous luminal surface) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim 29 is rejected under 35 U.S.C. 103(a) as unpatentable over Schwartz et al. in view of Cully et al. In response to applicant's argument that anyone considering the teaching of Schwartz et al. for a stent-graft (cannot serve in any pressure-resistant application that would allow leakage through the wall of the device between adjacent winding because the overlap portions are not sealed together) would not be considering the biliary graft teachings of Cully et al. (intended to be impermeable at relatively high pressures), the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it

that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Cully et al. is used as a secondary reference only to teach making at least one of the apices located between the ends of the stent component raised to protrude outwardly from the tubular form. Including a protruding apex, as taught by Cully et al., to the stent component of Schwartz et al. to provide the endoprosthesis with an anchoring means by the apex protruding slightly into the wall of the conduit into which it is implanted is neither taught away from by Schwartz et al., nor destructive to the endoprosthesis. The endoprosthesis will still remain tubular with inclusion of the protruding apex.

Allowable Subject Matter

Claim 23 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID J. ISABELLA

PRIMARY EXAMINER

DJI

Art Unit 3738